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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,569	10/27/2003	Stefan Henke	01-1405	3543

28501 7590 12/11/2008

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EXAMINER	
PURDY, KYLE A	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,569	HENKE ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/17/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 10/17/2008 wherein claim 25 has been newly added.

2. Claims 1-25 are pending, claims 21-24 are withdrawn and claims 1-20 and 25 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 10/17/2008 regarding the rejection of claims 1-20 made by the Examiner under 35 USC 103(a) over Bock et al. (EP 0945134) in view of Struengmann et al. (US 6284269) and Parikh (Handbook of Pharmacological Granulation Tech, 1997, 60-72) have been fully considered and are found persuasive. This rejection has been **WITHDRAWN.** However, since the Examiner has maintained the teaching of Bock in the new rejection, the merits of the reference will be discussed below.

4. In regards to the 103(a) rejection, Applicant asserts the following:

A) Bock does not teach or suggest that their granules would be water soluble as required be the instant claims.

5. In response to assertion A, the Examiner disagrees. Bock shows at least in one place that their granules are water soluble. Applicant is directed to Figure 4 which shows that drug plasma levels spike once the granular composition is administered. This indicates that the granular composition is water soluble as plasma is aqueous in nature. With respect to Figure 3, it is unclear what this is showing as Bock never teaches what medium the granules are actually being dissolved in. Moreover, as the composition of the granular composition is essentially identical to

that instantly claimed, in that it contains the same drug, meglumine, same carrier and same binder, one of ordinary skill would expect similar physical properties. Absent any secondary evidence, it is unclear to the Examiner how Applicants composition differs from teaching of Bock, with exception to the sweetener and optinal flavorant. In view of the above, Applicants arguments are not found persuasive.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claims 1-19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413).**

8. Bock is directed to oral meloxicam compositions. A granule formulation is disclosed in Example 7. The meloxicam granules comprise meloxicam, sodium citrate, lactose (carrier) (see instant claims 1 and 13-16), polyvinylpyrrolidone (povidone; a binder) (see instant claims 1, 3 and 4). It is taught that the meloxicam may be a sodium or megluine salt (see claim 1; see instant claims 1 and 2). The ratio between meglumine and meloxicam is taught to be from 1.2:1 to 1:1.2 (see instant claims 18 and 19).The concentration of meloxicam in the granules is about 3.5% by weight (see Example 7; see instant claim 17).

9. Bock fails to teach the composition as comprising a sweetener and an optional flavorant. Moreover, Bock fails to teach 5g of their meloxicam granules as being capable of dissolving in 100 mL of demineralized water within 1 minute.

10. Faour is directed to pharmaceutical composition containing a COX-II inhibitor and a muscle relaxant which may be in the form of a granule. An exemplified COX-II inhibitor is meloxicam (see claim 1). It is taught that the granular formulations are to comprise a flavorant such as apple and vanilla (see [0087]; see instant claims 9-12) and a sweetener such as a aspartame and saccharin (see [0074]; see instant claims 5-8). It is taught that these excipients are useful for including into such compositions to impart a sweetness and a pleasant flavor to the preparation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bock and Faour with a reasonable expectation for success in arriving at a water soluble granule composition comprising meloxicam meglumine, a binder, a sweetener, a carrier and an optional flavorant. Bock and the instant composition are essentially identical except for the lacking of the sweetener and optional flavorant, otherwise the compositions are identical. It is acknowledged that Bock does not teach 5 grams of their granules as possessing the ability to dissolve in 100 mL of water. However, because the compositions are essentially identical, except for the sweetener, one would expect both to have similar pharmacological and physical properties. The fact that Bock does not teach their granules as possessing such a property does not mitigate the applicability of teaching to the instant application. It is the position of the Examiner, absent any secondary evidence, that the granules of Bock possess similar dissolution properties as that instantly claimed as the formulas

are sufficiently alike in make up See MPEP 2112.01. With respect to the inclusion of a flavorant and a sweetener in the granule composition, this is obvious. One would be motivated to include such ingredients to impart a nice flavor to the composition when consumed by the user. Therefore, a water soluble granule comprising meloxicam, a binder, a carrier, a sweetener and an optional flavorant is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

11. **Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al. (US 6869948) in view of Faour et al. (US 2004/0204413) and Parikh (Handbook of Pharmaceutical granulation Technology, 1st edition, 1997, 60-72; of record).**

12. Bock and Faour are relied upon for disclosure described in the rejection of claims 1-19 and 25 under 35 U.S.C. 103(a).

13. As discussed above, Bock teaches a granular composition which comprises meloxicam, megluime, povidone (binder) and lactose (carrier).

14. Bock fails to teach a composition which comprises meloxicam, meglumine, hydroxypropylmethylcellulose, povidone and glucose monohydrate (dextrose).

15. Fauor teaches that the carrier for their granular composition may be lactose or dextrose. Fauor also teaches that the binder for the granular composition can be povidone (see [0076] and [0077]). It is also taught that other known materials can be utilized in the particle formulation and combinations may be used.

16. Parikh is drawn to a variety of binders to be used in granulating granules. It is taught that binders are provided to provide a cohesive force to the granules. Binders include natural and synthetic polymers such as povidone and hydroxypropyl methylcellulose (HPMC).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bock, Faour and Parikh with a reasonable expectation for success in arriving at a water soluble granule composition comprise meloxicam, meglumine, HPMC, povidone and glucose monohydrate. Albeit none of the references teach a composition with such properties, all of the ingredients are commonly used in the formulation of pharmaceutical granules. For instance, as discussed above, carriers such as lactose and glucose (dextrose) are interchangeable and binders such HPMC and povidone can be used together or by themselves. It would have been obvious to a person of ordinary skill in the art to look at the art and arrive at a composition with the instantly claimed components. With respect to the glucose being in the monohydrated form, this is obvious. Glucose (dextrose) are naturally found in the monohydrated form, so this requirement would be well within the purview to an ordinary skilled artesian. Therefore, a composition comprising meloxicam, meglumine, povidone, HPMC and glucose monohydrate is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
December 02, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611